C2 Base Hole Cover

Instructions for Use 111-072-357 Rev. B Issue Date: Sep-18

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Caution:

Carefully read all the instructions and be familiar with the surgical technique(s) prior to use of the system. This product must only be used by trained, qualified persons, aware of the directions for use. The C2 Base Hole Cover is compatible only with the C2 Acetabular Shell, as manufactured by Amplitude SAS.

Federal law restricts this device to sale, distribution and use by or on the order of a physcian.

1 Indications

The C2 Base Hole Cover is indicated strictly for use only with the C2 Acetabular Shell, as manufactured by Amplitude SAS. The C2 Base Hole Cover may be used in all cases where a surgeon has elected to use the C2 Acetabular Shell. Please refer to the instructions for use for the C2 Acetabular Shell for a complete set of indications for use applicable to the C2 Base Hole Cover.

2 Contraindications

The C2 Base Hole Cover is indicated strictly for use with the C2 Acetabular Shell, as manufactured by Amplitude SAS. The C2 Base Hole Cover is contraindicated for use with any other device. Therefore, the C2 Base Hole Cover shares the same contraindications for use as the C2 Acetabular Shell. Please refer to the instructions for use for the C2 Acetabular Shell for a complete set of indications for use applicable to the C2 Base Hole Cover.

3 Implant Selection Precautions

Selection of an implant of the correct size, shape and type of bone fixation is extremely important to maximise the potential for a successful, long term, outcome for the patient.

The C2 Base Hole Cover is intended strictly for use with the C2 Acetabular Shell, as manufactured by Amplitude SAS. The C2 Base Hole Cover is not compatible with any other device. Use of the C2 Base Hole Cover with devices other than the C2 Acetabular Shell, as manufactured by Amplitude SAS, is strictly prohibited.

4 Patient Selection Precautions

The following factors may be relevant to the success of the procedure:

- The patient's body mass. An obese patient may place increased loads on the prosthesis which can lead to failure of the device or loosening in the bone. The risk increases with smaller size implants and increasing patient weight.
- The patient's regular type and level of activity or employment may affect the durability of the components. If the patient's occupation or activity includes significant impact loads, the increased forces can cause failure of the implant or failure of the fixation of the device to bone. High levels of physical activity over time can accelerate the normal wear process that occurs with the bearing surface of prosthetic joints. Constrained liners are strongly recommended against use in active patients.
- Mental illness, or substance dependence which may tend to reduce the patients compliance with prescribed precautions and limitations on physical activities, which may cause implant failure or other complications.
- Material sensitivity. Patients should be screened for potential sensitivity to the constituent materials composing the device. If sensitivity is suspected, Preoperative tests should be conducted.

Please refer to the instructions for use for the C2 Acetabular Shell for further details.

5 Component Description and Compatibility

The C2 Base Hole Cover is individually sterile packed and designed for single patient use only.

The C2 Base Hole Cover is intended strictly for use with the C2 Acetabular Shell, as manufactured by Amplitude SAS. The C2 Base Hole Cover is not compatible with any other device. Use of the C2 Base Hole Cover with devices other than the C2 Acetabular Shell, as manufactured by Amplitude SAS, is strictly prohibited.

The C2 Base Hole Cover is intended to be used to cover the apical insertion hole of the C2 Acetabular Shell, as manufactured by Amplitdue SAS. The C2 Base Hole Cover is manufactured from titanium alloy.

6 Possible Adverse Effects

Wear: The bearing surfaces of components may wear with use over time. The presence of third body particles of bone cement, metal, bone or other materials which can develop as a result of the surgical procedure may cause abrasion of the articulating surfaces and lead to accelerated wear. Higher rates of wear may reduce the functional life of the hip replacement and result in the need for early revision surgery to replace the worn components.

Osteolysis: Progressive bone resorption or osteolysis may occur around the prosthetic components as a consequence of the body's immune reaction to particulate wear debris. Particles are generated by interaction between the prosthetic components, as well as between the components and bone interface. Particles may also be generated by third-body debris between the articulating surfaces. Osteolysis can lead to failure of the fixation between the implant and bone requiring the removal or replacement of the prosthetic components.

Structural Failure: Deformation or fracture of implant components may result from failure to observe the Warnings and Precautions contained herein. Fracture of the implant can also occur as a result of traumatic injury, acute excessive loading, or improper anatomical alignment.

Fracture: Pelvic or femoral: May occur intraoperatively, due to reaming, broaching or implant insertion. May occur postoperatively, due to prosthesis stress transfer caused by inappropriate early weight bearing or trauma.

Nerve Injury: Femoral, sciatic, peroneal nerve, and lateral femoral cutaneous nerve injury resulting in temporary or permanent nerve damage, with consequential pain or numbness of the affected limb.

Infection: Local or systemic, acute post-operative wound infection and late onset prosthetic infection.

Hematoma: Deep and superficial wound hematoma. Thromboembolic incidents including venous thrombosis, pulmonary embolus, cerebrovascular events or myocardial infarction.

Material Sensitivity: Metal sensitivity reactions and/or allergic reactions to foreign materials may occur.

Other possible adverse events include; decreased range of motion, dislocation, subluxation, leg length discrepancies, heterotopic bone formation, penetration of the femoral prosthesis through the femoral cortex, acetabular fracture, intrapelvic protrusion of the acetabular component or prosthetic femoral head, myositis ossificans or femoral impingement, vascular injury and/or delayed wound healing, excess femoral medialisation, or lateralisation, causing gait change or pain in the joints of the affected or contralateral extremity.

Please refer to the instructions for use for the C2 Acetabular Shell for further details.

WARNINGS AND PRECAUTIONS

Please refer to the instructions for use for the C2 Acetabular Shell for further warnings and precautions. Presented below are general warnings and precautions, typical of the hip replacement procedure.

7 Patient Consent

As with all surgical procedures, the patient should be made aware of the risks and possible adverse effects. In particular the patient should be warned of limitations of the prosthetic device components being implanted, including the limited expected service life of the device and the possible requirement for revision surgery to replace worn or damaged prostheses.

8 Operative Information

All devices should only be used according to the package directions in conjunction with the specified surgical technique and instructions for use. Additional warnings and precautions may be included in component literature. Please refer to the instructions for use for the C2 Acetabular Shell for further details.

9 Preoperative

Care should be taken when handling the prosthetic components to avoid damage to the surface of the device. Denting, notching or scratching can greatly reduce the tensile strength, fatigue resistance or wear properties of the component potentially leading to fracture or failure of the device.

Surgical technique information is available for each device component. The surgeon should familiarise themselves thoroughly with the technique prior to consideration of the use of the device for any specific patient.

Implants are only to be used with approved Amplitude Orthopaedics instrumentation and/or devices. The surgical instrumentation prescribed within the technique for the implantation of the prosthesis should not be used for any other device or in a manner contrary to its intended use. Failure or breaking of instruments can occur. Instruments have a limited service life and should be examined for wear or damage and replaced prior to surgery if required.

Instrumentation and implants should be sterilised according to the manufacturer's protocols. Do not resterilise component parts which have been assembled, or implants connected to surgical instruments. Do not cool hot components in cold water.

The patient should be warned about the potential adverse events associated with exposure to strong magnetic fields after implantation of device components made of stainless steel, cobalt chrome or titanium alloys. During MR imaging exposure to pulsed radio frequency fields can generate heat within tissue and metal components significant enough to cause serious burns. Metallic implants may create imaging artefacts or distortions to varying degrees in MR images.

Signature Orthopaedics does not recommend MR imaging for any patients implanted with metallic hip component(s) without prior consultation with an expert radiologist for assessment of potential adverse events such as device movement, localized burns, torsional or shear strain on the implanted device. The safety of the devices in the MR environment is unknown, and scanning of patients who have the device may result in patients' injuries (i.e. the device is MR unsafe).

10 Intraoperative

Correct implant selection is extremely important. The use of preoperative imaging, templating and the intraoperative use of trial components is recommended to facilitate the choice of an optimum size and type of component for the specific patient. The patients overall anatomical and medical condition should also be considered in conjunction with age, expected activity level, life expectancy and potential for future revision surgeries. The incorrect selection of implant type or size may result in failure of the component and/or bone.

The correct selection and positioning of the acetabular component and the choice of the appropriate neck length and/ or offset of the stem is important to prevent complications. Malposition of the components can result in loosening, dislocation or subluxation, of the joint.

Penetration of the inner cortex of the pelvis should be avoided when drilling for or placing screws for fixation of the acetabular component as damage to neurovascular structures may occur from the drill or screws of excessive length. Similarly, drilling and/or placing screws in the acetabular prosthesis when oriented in an anterior or medial direction, is associated with a high risk of serious vascular injury. Screws must be completely seated in the shell to allow proper seating for the acetabular liner.

The stem taper must be clean and dry prior to impacting the femoral head or taper sleeve or postoperative separation of the head from the stem may occur.

Use only system indicated titanium bone screws and hole covers with the same system acetabular components. Refer to product literature for proper adjunctive fixation and hole cover usage. The C2 Base Hole Cover is intended strictly for use with the C2 Acetabular Shell, as manufactured by Amplitude SAS. The C2 Base Hole Cover is not compatible with any other device. Use of the C2 Base Hole Cover with devices other than the C2 Acetabular Shell, as manufactured by Amplitude SAS, is strictly prohibited.

Before assembly of components, surgical debris must be cleaned from the surfaces. Debris, including bone cement, may inhibit the component coupling mechanism. When inserting acetabular liners, ensure soft tissue does not impinge between the shell and liner. Modular components such as femoral heads and taper sleeves must be assembled securely to prevent disassociation. Incorrectly seated acetabular liners may loosen and disassociate from the shell.

Repeated assembly and disassembly of the modular components should be avoided as this could compromise the locking mechanism. Acetabular Cup Liners cannot be reused once removed from the Acetabular Cup, as removal permanently damages the locking mechanism on the liner.

Implants removed from the patient at revision surgery should never be reimplanted as the fatigue state of the implant cannot be determined by visual examination. Removed implants must be treated as biological hazards and are required to be treated or disposed of according to the waste regulations of the country where the implant is removed.

The wound site should be thoroughly cleaned of cement, bone and other debris before closure. Range of motion should also be assessed before closure. Osteophytes, ectopic bone or old scar tissue causing impingement should be removed to reduce the possibility of reduced range of motion or dislocation.

11 Precautions for Specific Conditions

A higher incidence of sciatic nerve palsy is associated with arthroplasty in the treatment of congenitally dislocated hips. Also, in such patients, a pseudoacetabulum should not be utilized as a placement site for the acetabular cup.

12 Postoperative Care

It is extremely important that patients are provided with clear directions regarding the extent, type and progression of post operative physical activity. The level of weight bearing should be determined for the individual patient depending on the type of procedure and components used. In the event of bone grafting or extensive revision surgery a non-weight bearing period should be considered.

Patients should be warned against unassisted activity, particularly the use of bathing and toilet facilities and other activities requiring significant non-gait motion of the hip.

When manual patient handling is required, care should be taken to support the operative leg and pelvis to minimise the risk of dislocation.

The use of post operative physiotherapy is recommended to rehabilitate the muscles affecting hip function as physical activity is increased.

Staged follow up with x-ray comparison to the immediate postoperative imaging is recommended to detect evidence of detrimental change in the implant. Any indication of structural failure of the implant, radiolucencies, or osteolysis should be monitored carefully for the potential need of early revision surgery.

The patient should be advised that prophylactic antibiotics therapy may be required for subsequent treatments, procedures, or situations which may result in bacteremia.

13 Packaging and Labeling

Components should only be used if the factory packaging and labeling are intact. If the sterile barrier has been broken, return the component to Amplitude SAS.

14 Sterilization and Resterilization

Implants are supplied sterile and have been double sterile packaged. The method of sterilisation is noted on the package label. Dispose of the implant if the packaging is damaged. Resterilisation of the implants is not recommended, as it may alter the mechanical integrity of the device.

Unless specifically labelled sterile, instruments are supplied non-sterile and must be sterilised prior to use.

A complete guide for reprocessing reusable instruments may be provided upon request.

Please refer to the instructions for use for the C2 Acetabular Shell for further details.

15 Cleaning

Implants are supplied sterile and intended for single use only. Dispose of the implant if the packaging is damaged. Cleaning of the implants is not recommended.

Re-usable instruments are delivered non-sterile. A complete guide for reprocessing reusable instruments may be provided upon request.

Please refer to the instructions for use for the C2 Acetabular Shell for further details.

16 Storage and Handling

Implants and instruments are to be stored in dry, clean surroundings at room temperature, in their original packaging or sterilisation tray respectively.

17 Limited Warranty / Liability

Signature Orthopaedics Europe. Ltd. products are sold with a limited warranty to the original purchaser against defects in workmanship and materials. Any other express or implied warranties, including warranties of merchantability or fitness, are hereby disclaimed.

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18 Contact Information

If more than 2 years have elapsed between the date of issue/revision of this document, and the date of patient consultation, contact the appropriate Signature Orthopaedics location for current information.

For further information or questions pertaining to sales and service, please contact your local sales representative or the appropriate Signature Orthopaedics location as listed below:

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